



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-545

Alcon, Inc.  
c/o Alcon Research, Ltd.  
Attention: Angela C. Kothe, O.D., Ph.D.  
Associate Director, Regulatory Affairs  
6201 South Freeway  
Fort Worth, TX 76134-2099

Dear Dr. Kothe:

Please refer to your new drug application (NDA) dated August 14, 2002, received August 15, 2002, submitted under section 505 (b) (1) of the Federal Food, Drug, and Cosmetic Act for olopatadine hydrochloride ophthalmic solution, 0.2%.

We acknowledge receipt of your submissions dated November 5, 19, and December 9, 13, and 17, 2004. The November 5, 2004, submission constituted a complete response to our June 4, 2004, action letter.

This new drug application provides for the use of olopatadine hydrochloride ophthalmic solution, 0.2% for the treatment of ocular itching associated with allergic conjunctivitis.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert, immediate container and carton labels) submitted December 17, 2004, with the additional changes agreed on in the teleconference on December 21, 2004. These changes are listed below:

- 1) The word oval should be included in the bottle description in the How Supplied section of the package insert.
- 2) The preservative should be moved to the Inactives section on both cartons consistent with the proposed package insert.

Marketing the product with FPL that is not identical to the approved labeling text with the changes mentioned above may render the products misbranded and an unapproved new drug.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the

following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling is to be submitted in *pdf* format. In future submissions, to assist in our review, we request that labeling also be submitted in MS Word format with proposed revisions clearly indicated, preferably in track changes. If formatted copies of all labeling pieces are submitted electronically, labeling does not need to be submitted in paper.

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA*. Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,  
and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Alison Rodgers, Regulatory Project Manager, at (301) 827-2019.

Sincerely,

*{See appended electronic signature page}*

Wiley A. Chambers, M.D.  
Deputy Director  
Division of Anti-Inflammatory, Analgesic, and  
Ophthalmic Drug Products, HFD-550  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research

Enclosure

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/s/

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Wiley Chambers

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